

EXHIBIT 6

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

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)
THE PROIMMUNE COMPANY, LLC, derivatively)
on behalf of INNATE FFAAP MEDICINE LLC and)
STRESS WATCHERS OXIDATIVE STRESS TEST)
METHOD LLC, and INNATE FFAAP MEDICINE)
LLC, derivatively on behalf of PROTHIONE LLC)
and LIPINOL LLC,)
)
Plaintiffs,)
)
v.)
)
LAURA LILE, M.D., and THREE AMINOS, LLC,)
)
Defendants,)
Counterclaimants, and)
Third-Party Plaintiffs,)
)
v.)
)
ALBERT CRUM, M.D.,)
)
Third-Party Defendant.)
-----)

)
)
Index No. 653093/2022

DEFENDANTS’ VERIFIED
ANSWER WITH
COUNTERCLAIMS AGAINST
PLAINTIFF PROIMMUNE AND
CROSS-CLAIMS AGAINST
THIRD-PARTY DEFENDANT
ALBERT CRUM, M.D.

JURY TRIAL DEMANDED

DEFENDANTS’ VERIFIED ANSWER, DEFENSES, COUNTERCLAIMS AND CROSS-CLAIMS AGAINST THIRD-PARTY DEFENDANT ALBERT CRUM, M.D.

Defendants-Counterclaimants and Third-Party Plaintiffs, Laura Lile, M.D. (“Dr. Lile”) and Three Aminos, LLC (“Three Aminos”) (collectively referred to as “Defendants” in the Answer and as “Counterclaimants” in the Counterclaims), by and through their undersigned counsel, Answer the Complaint of Plaintiffs, the ProImmune Company, LLC (“ProImmune”), derivatively on behalf of Innate FFAAP Medicine LLC (“Innate”) and Stress Watchers Oxidative Stress Test Method LLC (“Stress Watchers”), and Innate FFAAP Medicine LLC, derivatively on behalf of Prothione LLC (“Prothione”) and Lipinol LLC (“Lipinol”); Counterclaim against

Plaintiff ProImmune; and Cross-claim against Third-Party Defendant Albert Crum, M.D. as follows:

ALLEGED NATURE OF THE ACTION

1. Defendants admit that the Complaint purports to assert causes of action arising from purported agreements between Dr. Albert Crum and Dr. Laura Lile. Defendants deny that Dr. Laura Lile personally entered into any binding contractual obligations as alleged in this paragraph or that she or Three Aminos failed to uphold any obligations. The remaining allegations in this paragraph consist of legal conclusions and Defendants hereby deny them. Except as expressly admitted, Defendants deny each and every allegation in paragraph 1 of the Complaint.

2. Defendants deny that Immune Formulation 200® is a patented product. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore deny them.

3. Defendants admit that Dr. Lile founded Three Aminos. Except as expressly admitted, Defendants deny each and every allegation in paragraph 3 of the Complaint.

4. Defendants admit that the Complaint purports to describe a series of contracts, which the Complaint attaches as Exhibits, relating to formulations incorporating Immune Formulation 200® and a purported device related to the same product. Defendants refer to the purported contracts for their terms, and state that Plaintiffs have mischaracterized the terms of the contracts. Except as expressly admitted, Defendants deny each and every allegation in paragraph 4 of the Complaint.

5. Defendants refer to the purported contracts referenced in the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the contracts. Defendants

expressly deny that ProImmune provided any consideration in inducing any Defendant to enter these contracts and deny that ProImmune owns any intellectual property rights in the Immune Formulation supplement formula. Except as expressly admitted, Defendants deny each and every allegation in paragraph 5 of the Complaint.

6. Defendants refer to the purported contracts referenced in the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the contracts. Defendants expressly deny that Defendants breached any contractual obligations. Except as expressly admitted, Defendants deny the remaining allegations in this paragraph.

7. Defendants refer to the purported contracts referenced in the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the contracts. Defendants expressly deny that Defendants breached any contractual obligations. Except as expressly admitted, Defendants deny the remaining allegations in this paragraph.

8. Denied.

9. Defendants admit that they have negotiated in good faith to resolve the dispute between Plaintiffs and Defendants. Except as expressly admitted, Defendants deny each and every allegation in this paragraph.

PARTIES

10. Defendants admit the allegations contained in Paragraph 10 of the Complaint.

11. Defendants admit the allegations contained in Paragraph 11 of the Complaint.

12. Defendants admit that ProImmune purports to own a 50% interest in Innate and Stress Watchers. Defendants are without sufficient information or belief to admit or deny the remaining allegations of this paragraph and therefore deny them.

13. Defendants admit that Stress Watchers is a Delaware limited liability company with its principal place of business in Franklin, Tennessee. Except as expressly admitted, Defendants deny each and every allegation in paragraph 13 of the Complaint.

14. Defendants admit that Prothione LLC is a Delaware limited liability company with a principal place of business in Franklin, Tennessee. Except as expressly admitted, Defendants deny each and every allegation in paragraph 14 of the Complaint.

15. Defendants admit that Lipinol LLC is a Delaware limited liability company a principal place of business in Franklin, Tennessee. Except as expressly admitted, Defendants deny each and every allegation in paragraph 15 of the Complaint.

16. Defendants admit the allegations contained in Paragraph 16 of the Complaint.

17. Defendants admit that Dr. Lile is an individual. Except as expressly admitted, Defendants deny each and every allegation in paragraph 17 of the Complaint.

18. Defendants admit the allegations contained in Paragraph 18 of the Complaint.

ALLEGED JURISDICTION AND VENUE

19. Defendants admit that this Court has jurisdiction over Defendants. Defendants deny the remaining allegations in paragraph 19 of the Complaint.

20. Defendants admit that venue is proper in this Court prior to removal and in the Southern District of New York after removal. Defendants deny the remaining allegations in paragraph 20 of the Complaint.

ALLEGED FACTUAL BACKGROUND

21. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 21 of the Complaint, and therefore deny them.

22. Paragraph 22 does not contain any allegations directed towards the Defendants and therefore no response is required. To the extent a response is required, the Defendants admit

that glutathione is present in the human body and serves numerous functions. Defendants further admit that Dr. Crum has been involved in studying and developing the FFAAP method as well as Immune Formulation 200. Except as expressly admitted, Defendants deny each and every allegation in paragraph 22 of the Complaint.

23. Defendants admit that Immune Formulation 200 is a blend of selenium and amino acids and has been the subject of research. Except as expressly admitted, Defendants deny the remains allegations in paragraph 23 of the Complaint.

24. Defendants admit that, in the United States, dietary supplements such as Immune Formulation 200® cannot be marketed as a treatment or cure to diseases. Defendants admit that it is possible to seek FDA approval for dietary supplements as a pharmaceutical drug. Except as expressly admitted, Defendants deny each and every allegation in paragraph 24 of the Complaint.

25. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 25 of the Complaint, and therefore deny them.

26. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26 of the Complaint, and therefore deny them.

27. Defendants admit that Dr. Lile attended a meeting at the Harvard Club of New York City on March 6, 2020 related to glutathione and that she has worked with the Vatican. Except as expressly admitted, Defendants deny each and every allegation in paragraph 27 of the Complaint.

28. Defendants admit that Dr. Lile has referred to the FFAAP method as revolutionary. Except as expressly admitted, Defendants deny each and every allegation in paragraph 28 of the Complaint.

29. Defendants admit that Dr. Lile founded Three Aminos. Dr. Lile admits that Three Aminos became a distributor of Immune Formulation 200. Except as expressly admitted, Defendants deny each and every allegation in paragraph 29 of the Complaint.

30. Defendants admit that Dr. Crum required Dr. Lile to hold daily or nearly daily phone calls with Dr. Crum to discuss topics including the FFAAP method, Immune Formulation 200®, and/or the science underlying each. Except as expressly admitted, Defendants deny each and every allegation in paragraph 30 of the Complaint.

31. Defendants admit that Dr. Crum and Dr. Lile had numerous telephone calls between March and November 2020, and that Dr. Crum consistently expressed his desire to have Dr. Lile become more involved with ProImmune. Defendants admit that Dr. Crum convinced Dr. Lile to try and get Immune Formulation 200® approved by the FDA as a pharmaceutical drug. Except as expressly admitted, Defendants deny each and every allegation in paragraph 31 of the Complaint.

32. Defendants admit that Dr. Crum and Dr. Lile had numerous telephone calls between March and November 2020, and that Dr. Crum consistently expressed his desire to have Dr. Lile obtain FDA approval for Immune Formulation 200®. Defendants admit that Dr. Lile is a person of devout faith and that she conducts her business dealings with a strong sense of morality. Except as expressly admitted, Defendants deny each and every allegation in paragraph 32 of the Complaint.

33. Defendants admit that the Complaint purports to attach a series of agreements and that the parties had numerous other agreements not attached to the Complaint. Except as expressly admitted, Defendants deny each and every allegation in paragraph 33 of the Complaint.

34. Defendants admit that Exhibit 1 attached to the Complaint purports to be an Oxidative Stress Kit Commercialization Agreement. Defendants refer to Exhibit 1 in the Complaint for its terms, and state that Plaintiffs have mischaracterized the terms of the purported agreement. Except as expressly admitted, Defendants deny each and every allegation in paragraph 34 of the Complaint.

35. Defendants admit that Three Aminos paid \$5 million to ProImmune under false pretenses. Defendants refer to the purported agreements referenced in the Complaint for their terms, and state that Plaintiffs have mischaracterized their terms. Defendants expressly deny that Defendants breached any contractual obligations. Except as expressly admitted, Defendants deny each and every allegation in paragraph 35 of the Complaint.

36. Defendants admit that Exhibit 2 attached to the Complaint purports to be a Pharmaceutical Commercialization Agreement. Defendants refer to Exhibit 2 in the Complaint for its terms, and state that Plaintiffs have mischaracterized the terms of the purported agreement. Defendants admit that Exhibit 3 attached to the Complaint purports to be an Operating Agreement for Innate. Except as expressly admitted, Defendants deny each and every allegation in paragraph 36 of the Complaint.

37. Defendants admit the allegations contained in Paragraph 37 of the Complaint.

38. Defendants admit that Prothione and Lipinol are each wholly owned by Innate. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 38 of the Complaint.

39. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as

expressly admitted, Defendants deny each and every allegation in paragraph 39 of the Complaint.

40. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 40 of the Complaint.

41. Defendants refer to Exhibits 4 and 5 attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 41 of the Complaint.

42. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 42 of the Complaint.

43. Defendants admit that seeking FDA approval requires extensive work, including testing and a Phase III clinical trial. Defendants admit that Dr. Lile and Dr. Crum discussed a high-level plan. Except as expressly admitted, Defendants deny each and every allegation in paragraph 43 of the Complaint.

44. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 44 of the Complaint.

45. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Defendants

admit the purported Board of Innate comprises Drs. Crum and Lile. Except as expressly admitted, Defendants deny each and every allegation in paragraph 45 of the Complaint.

46. Defendants admit that Dr. Lile is named as CEO of Prothione and Lipinol. Except as expressly admitted, Defendants deny each and every allegation in paragraph 46 of the Complaint.

47. Defendants admit that Dr. Lile believed there was a chance that the formulations for the treatment of COVID-19 and high cholesterol would be approved by the FDA and that they could provide a source of revenue. Defendants admit that FDA approval is not guaranteed. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 47 of the Complaint, and therefore deny them.

48. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 48 of the Complaint, and therefore deny them.

49. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 49 of the Complaint, and therefore deny them.

50. Defendants admit that Dr. Lile believed there was a chance that the formulations would be approved by the FDA and that they could provide a source of revenue. Defendants admit that Dr. Lile reviewed published scientific research on glutathione and Immune Formulation 200® and that she has provided Immune Formulation 200® as a supplement to some patients in her private medical practice. Except as expressly admitted, Defendants deny each and every allegation in paragraph 50 of the Complaint.

51. Defendants admit that Dr. Lile conducted a Phase II trial of Prothione in Rwanda. The results of that trial speak for themselves. Except as expressly admitted, Defendants deny each and every allegation in paragraph 51 of the Complaint.

52. Defendants admit that Dr. Lile believed there was a chance that the formulations could generate significant annual sales. Defendants admit that there are markets for COVID-19 and dyslipidemia treatments. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 52 of the Complaint, and therefore deny them.

53. Defendants admit that Dr. Lile posted the graphic appearing in paragraph 53 of the Complaint to prothionecaps.com and that the posting speaks for itself. Except as expressly admitted, Defendants deny each and every allegation in paragraph 53 of the Complaint.

54. Defendants deny that they failed to comply with any purported contractual obligations. Defendants deny that they materially breached any purported agreement with ProImmune. Defendants deny any further allegations in paragraph 54 of the Complaint.

55. Defendants deny each and every allegation in paragraph 55 of the Complaint.

56. Defendants deny each and every allegation in paragraph 56 of the Complaint.

57. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 57 of the Complaint.

58. Defendants admit that Dr. Lile performed substantial work under the purported agreements under false pretenses and that Three Aminos provided substantial funding for Prothione under false pretenses. Defendants deny that Dr. Lile has been negligent in executing any of her duties as the CEO and Director of Prothione. Defendants admit that a Phase II study has been completed for Prothione and that an IND has not been filed with the FDA because Dr. Crum has been completely non-responsive since May 2022. Except as expressly admitted, Defendants deny each and every allegation in paragraph 58 of the Complaint.

59. Defendants deny each and every allegation in paragraph 59 of the Complaint.

60. Defendants deny each and every allegation in paragraph 60 of the Complaint.

61. Defendants deny each and every allegation in paragraph 61 of the Complaint.

62. Defendants deny that Dr. Crum complained about alleged contractual violations.

Except as expressly admitted, Defendants deny each and every allegation in paragraph 62 of the Complaint.

63. Defendants admit that the parties had a teleconference in December 2021.

Except as expressly admitted, Defendants deny each and every allegation in paragraph 63 of the Complaint.

64. Defendants deny each and every allegation in paragraph 64 of the Complaint.

65. Defendants admit that Prothione issued a press release in July 2022 as partially reproduced in paragraph 65 of the Complaint, and that the press release speaks for itself. Except as expressly admitted, Defendants deny each and every allegation in paragraph 65 of the Complaint.

66. Defendants admit that Prothione issued a press release in July 2022 as partially reproduced in paragraph 65 and partially quoted in paragraph 66 of the Complaint, and that the press release speaks for itself. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 66 of the Complaint, and therefore deny them.

67. Defendants deny that Immune Formulation 200® is not also known as IF200® because Dr. Crum has himself used IF200® in communications, including communications to Dr. Lile. Defendants admit that Three Aminos applied to register IF200 as a trademark and did not do so secretly. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 67 of the Complaint, and therefore deny them.

68. Defendants deny each and every allegation in paragraph 68 of the Complaint.
69. Defendants admit that the website describes Dr. Lile as “a rarity in the medical field . . . [who] has pioneered revolutionary formulations for her clients.” Defendants admit that Image 3 in the Complaint depicts a portion of the website. Except as expressly admitted, Defendants deny each and every allegation in paragraph 69 of the Complaint.
70. Defendants admit that Three Aminos applied to register IF200 as a trademark and that the application lists Dr. Lile’s email address, as well as her daughter’s email address, is listed for the correspondent email. Except as expressly admitted, Defendants deny each and every allegation in paragraph 70 of the Complaint.
71. Defendants deny each and every allegation in paragraph 71 of the Complaint.
72. Defendants deny each and every allegation in paragraph 72 of the Complaint.
73. Defendants deny each and every allegation in paragraph 73 of the Complaint.
74. Defendants deny each and every allegation in paragraph 74 of the Complaint

COUNT 1

75. Defendants incorporate each of the foregoing paragraphs as though fully set forth herein.
76. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 76 of the Complaint.
77. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 77 of the Complaint.

78. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 78 of the Complaint.

79. Defendants deny each and every allegation in paragraph 79 of the Complaint.

80. Defendants deny each and every allegation in paragraph 80 of the Complaint.

81. Defendants deny each and every allegation in paragraph 81 of the Complaint.

82. Defendants deny each and every allegation in paragraph 82 of the Complaint.

83. Defendants deny each and every allegation in paragraph 83 of the Complaint.

COUNT 2

84. Defendants incorporate each of the foregoing paragraphs as though fully set forth herein.

85. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 85 of the Complaint.

86. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Defendants admit that Innate is the sole member of Prothione. Except as expressly admitted, Defendants deny each and every allegation in paragraph 86 of the Complaint.

87. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 87 of the Complaint.

88. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 88 of the Complaint.

89. Defendants deny each and every allegation in paragraph 89 of the Complaint.

90. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 90 of the Complaint.

91. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 91 of the Complaint.

92. Defendants deny each and every allegation in paragraph 92 of the Complaint.

93. Defendants deny each and every allegation in paragraph 93 of the Complaint.

94. Defendants deny each and every allegation in paragraph 94 of the Complaint.

95. Defendants deny each and every allegation in paragraph 95 of the Complaint.

96. Defendants deny each and every allegation in paragraph 96 of the Complaint.

97. Defendants deny each and every allegation in paragraph 97 of the Complaint.

98. Defendants deny each and every allegation in paragraph 98 of the Complaint.

COUNT 3

99. Defendants incorporate each of the foregoing paragraphs as though fully set forth herein.

100. Paragraph 100 states a legal conclusion to which no response is required. To the extent any response is required, Defendants deny each and every allegation in paragraph 100 of the Complaint.

101. Defendants deny each and every allegation in paragraph 101 of the Complaint.

102. Defendants deny each and every allegation in paragraph 102 of the Complaint.

COUNT 4

103. Defendants incorporate each of the foregoing paragraphs as though fully set forth herein.

104. Paragraph 104 states a legal conclusion to which no response is required. To the extent any response is required, Defendants deny each and every allegation in paragraph 104 of the Complaint.

105. Defendants deny each and every allegation in paragraph 105 of the Complaint.

106. Defendants deny each and every allegation in paragraph 106 of the Complaint.

COUNT 5

107. Defendants incorporate each of the foregoing paragraphs as though fully set forth herein.

108. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 108 of the Complaint.

109. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Defendants admit that Innate is the sole member of Lipinol. Except as expressly admitted, Defendants deny each and every allegation in paragraph 109 of the Complaint.

110. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 110 of the Complaint.

111. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 111 of the Complaint.

112. Defendants deny each and every allegation in paragraph 112 of the Complaint.

113. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Defendants deny that they entered into any valid, legal, or binding agreements with ProImmune. Except as expressly admitted, Defendants deny each and every allegation in paragraph 113 of the Complaint.

114. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 114 of the Complaint.

115. Defendants deny each and every allegation in paragraph 115 of the Complaint.

116. Defendants deny each and every allegation in paragraph 116 of the Complaint.

117. Defendants deny each and every allegation in paragraph 117 of the Complaint.

118. Defendants deny each and every allegation in paragraph 118 of the Complaint.

119. Defendants deny each and every allegation in paragraph 119 of the Complaint.

120. Defendants deny each and every allegation in paragraph 120 of the Complaint.

121. Defendants deny each and every allegation in paragraph 121 of the Complaint.

COUNT 6

122. Defendants incorporate each of the foregoing paragraphs as though fully set forth herein.

123. Paragraph 123 states a legal conclusion to which no response is required. To the extent any response is required, Defendants deny each and every allegation in paragraph 123 of the Complaint.

124. Defendants deny each and every allegation in paragraph 124 of the Complaint.

125. Defendants deny each and every allegation in paragraph 125 of the Complaint.

COUNT 7

126. Defendants incorporate each of the foregoing paragraphs as though fully set forth herein.

127. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 127 of the Complaint.

128. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Defendants admit that Innate is the sole member of Prothione. Except as expressly admitted, Defendants deny each and every allegation in paragraph 128 of the Complaint.

129. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 129 of the Complaint.

130. Defendants refer to the Exhibits attached to the Complaint for their terms, and state that Plaintiffs have mischaracterized the terms of the purported agreements. Except as expressly admitted, Defendants deny each and every allegation in paragraph 130 of the Complaint.

131. Defendants deny each and every allegation in paragraph 131 of the Complaint.

132. Defendants deny each and every allegation in paragraph 132 of the Complaint.

133. Defendants deny each and every allegation in paragraph 133 of the Complaint.

134. Defendants deny each and every allegation in paragraph 134 of the Complaint.

135. Defendants deny each and every allegation in paragraph 135 of the Complaint.

COUNT 8

136. Defendants incorporate each of the foregoing paragraphs as though fully set forth herein.

137. Paragraph 137 states a legal conclusion to which no response is required. To the extent any response is required, Defendants deny each and every allegation in paragraph 137 of the Complaint.

138. Defendants deny each and every allegation in paragraph 138 of the Complaint.

139. Defendants deny each and every allegation in paragraph 139 of the Complaint.

Defendants deny that Plaintiffs have suffered any damages or are entitled to any of the relief requested in the unnumbered “Wherefore” paragraph immediately following paragraph 139 of the Complaint. Defendants deny that Plaintiffs are entitled to any other form of relief.

Defendants further deny each prayer for relief in paragraphs a-g.

DEFENSES AND AFFIRMATIVE DEFENSES

Defendants assert the following defenses without assuming the burden of proof where such burden is lawfully borne by Plaintiff and reserves the right to withdraw, amend and/or

supplement their defenses, including without limitation based upon information learned through investigation or the discovery process, or as otherwise warranted.

FIRST DEFENSE

1. The Complaint and each cause of action contained therein fails to state a claim upon which relief may be granted because Plaintiffs lack standing as third-party beneficiaries to bring various causes of action and also fail to sufficiently allege recoverable damages. The Complaint is legally and factually insufficient and must be dismissed.

SECOND DEFENSE

2. Plaintiffs' claims are barred by the doctrines of unclean hands, laches, and estoppel because, among other things, Plaintiff ProImmune and Third-Party Defendant Dr. Crum falsely represented that the Immune Formulation 200 is patented.

THIRD DEFENSE

3. Plaintiffs' claims are barred in whole or in part by its failure to mitigate any damages it may have suffered.

FOURTH DEFENSE

4. Plaintiffs' damages, to the extent they suffered any damages, are the result of its own conduct and/or the conduct of third parties over whom Defendant exercises no control.

FIFTH DEFENSE

5. Plaintiffs' damages, to the extent they suffered any damages, are limited by the purported agreements.

SIXTH DEFENSE

6. Plaintiffs' claims are barred by the termination, expiration, and/or invalidity of the purported agreements. The purported agreements are illusory because they are not supported by any consideration on the part of Plaintiff ProImmune, and therefore they are unenforceable.

SEVENTH DEFENSE

7. Plaintiffs' claims are barred in whole, or in part, because the purported agreements were fraudulently induced, invalid, and/or based on mistake.

EIGHTH DEFENSE

8. Plaintiffs' claims are barred in whole, or in part, by its express and/or implied waiver in seeking to enforce the purported agreements.

NINTH DEFENSE

9. Plaintiffs' claims are barred and/or not ripe for its failure to comply with conditions precedent.

TENTH DEFENSE

10. Defendants were excused from performance due to Plaintiffs' fraudulent inducement, material breach and/or anticipatory repudiation of the purported agreements.

ELEVENTH DEFENSE

11. Plaintiffs' claims are barred in whole or part because any alleged breach by Defendants was immaterial.

TWELFTH DEFENSE

12. Plaintiffs' claims are barred in whole or in part due to impossibility and/or impracticability.

THIRTEENTH DEFENSE

13. Plaintiffs lack standing because they are not parties to various agreements and cannot bring claims as third-party beneficiaries.

WHEREFORE, Defendants respectfully request that:

a. Plaintiffs take nothing by reason of the Complaint, the Complaint be dismissed in its entirety with prejudice, and that judgment be entered for Defendants;

- b. Defendants be awarded all attorneys' fees recoverable by law; and
- c. Defendants be awarded such other and further relief deemed just and proper.

COUNTERCLAIMS

INTRODUCTION

Defendants-Counterclaimants and Third-Party Plaintiffs, Dr. Lile and Three Aminos, (collectively referred to as "Counterclaimants") allege the following counterclaims and third-party claims against Cross-Defendant ProImmune Company, LLC ("ProImmune") and Third-Party Defendant Albert Crum, M.D. ("Dr. Crum") (collectively referred to as "Counterclaim-Defendants"):

PARTIES

- 1. Counterclaimants Three Aminos is a Georgia limited liability company with its principal place of business in Franklin, Tennessee.
- 2. Counterclaimant Laura Lile, M.D. is an individual residing in Franklin, Tennessee, and she is the founder of Three Aminos.
- 3. Counterclaim-Defendant ProImmune is, on information and belief, a Delaware limited liability company with its principal place of business in Rhinebeck, Dutchess County, New York.
- 4. Third-Party Defendant Albert Crum, M.D., is an individual who, on information and belief, resides in Dutchess County, New York. ProImmune and Dr. Crum are collectively referred to in these Counterclaims as Defendants.

JURISDICTION AND VENUE

- 5. Counterclaimants allege cross-claims and third-party claims for declaratory relief, patent invalidity, patent unenforceability, patent misuse, and additional cross-claims that arise

under the patent laws and over which a federal court would have federal question jurisdiction under 28 U.S.C. § 1331.

6. Counterclaim-Defendants are subject to this Court's personal jurisdiction pursuant to CPLR 301, and the personal jurisdiction of the District Court for the Southern District of New York, because they are doing business in New York, and have consented to personal jurisdiction in this Court and in the District Court for the Southern District of New York. Alternatively, Counterclaim-Defendants are subject to personal jurisdiction in accordance with CPLR 302 because they entered purported oral or written contacts to supply good or services in New York or committed tortious conduct within and without the state that have a substantial impact on interstate commerce and effects in the State.

7. Venue is proper in this County under CPLR 501, and in the District Court for the Southern District of New York pursuant to 28 U.S.C. §§ 1391 and 1400 because a substantial part of the events or omissions giving rise to the claims occurred in this County and in the District Court for the Southern District of New York, and because the Counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act.

FACTUAL ALLEGATIONS

Dr. Lile's Expertise, Reputation, and Notoriety

8. Dr. Lile is a board-certified medical doctor and registered compounding pharmacist with decades of experience. Dr. Lile has pioneered revolutionary formulations for her patients and devoted more than three decades to developing, teaching, and practicing the principles of preventive healthcare and wellness.

9. Dr. Lile is a sought-after expert in the field of longevity and immune system optimization. Dr. Lile's practice spans over forty states and serves thousands of patients. Dr.

Lile has been invited to educate her fellow doctors since 1995, and she is an award-winning member of six National and Global associations.

10. Dr. Lile has worked with the Vatican medical advisory group and met with His Holiness Pope Francis in November, 2019 as part of that work. She was later designated to collaborate on the Vatican Commission on COVID-19, established and supported Pope Francis. The designation acknowledged that Dr. Lile has achieved excellence in the medical field and has demonstrated a lifetime commitment to exemplary care for people.

Dr. Lile's Introduction to Dr. Crum and His Manipulating Tactics

11. On January 23, 2020, Dr. Lile received a Woman's Achievement Award in San Diego for her tireless work in the medical field. An attendee at the event approached Dr. Lile regarding a 90-year-old doctor (who turned out to be Dr. Crum) who also supposedly had ties to the Vatican and wanted to pass his supposed life's work on to someone that could carry it forward for the greater good. The attendee told Dr. Lile that this aging doctor—Dr. Crum—would want to meet her in New York City.

12. In February 2020, Alan Ogden of the Glutathione Authority forwarded Dr. Lile an email from Dr. Crum referencing a recent notice of allowance of patent claims. Dr. Crum referred to the allowed claims as a “[m]ajor development with world implications,” and stated: “Let us give Thanks to God for this development and to those dedicated individuals who prayed for and inspired this Project and the many other committed individuals who moved it forward with enthusiasm day by day. The above includes Saint Mother Teresa, the Dalai Lama XIV of Tibet, Archbishop Desmond Tutu and Pastor Luis Perez.”

13. On March 1, 2020, Dr. Lile spoke with Dr. Crum for the first time via a conference call. On the call, Dr. Crum and Dr. Lile discussed the Immune Formulation 200 and

a potential use to treat COVID-19. Dr. Lile mentioned to Dr. Crum that she was in close contact with the Vatican.

14. On March 2, 2020, Dr. Crum Express Mailed two containers of Immune Formulation 200 to Dr. Lile for transmittal to the Vatican. On March 3, 2020, Dr. Crum emailed Dr. Lile informing her of the incoming package, stating “we Express Mailed to you two containers of Immune Formulation 200® packaged for transmittal to the Vatican.” The email noted that the label on each container included the following: US Patent RE42,645/RE39,734E. Dr. Crum also attached numerous scientific articles related to glutathione.

15. Dr. Lile responded to the email the next day, and in response to that email, Dr. Crum stated, in part, “Dear Dr. Lile, Thank you for your Email. You were very perceptive as to the novel therapeutic potential that physiologically synthesized Glutathione can provide to inhibit pathogenic viruses, including Corona.”

16. On March 5, 2020, Dr. Crum sent Dr. Lile a lengthy email discussing the alleged greatness of his work and product.

17. On March 6, 2020, Dr. Lile attended a meeting at the Harvard Club of New York City, where she met Dr. Crum in person for the first time. Within minutes of meeting, Dr. Crum asked Dr. Lile to sit at the main table with him. When Dr. Lile tried to sit at the far end of the main table, Dr. Crum insisted that she sit next to him, centerstage. And so began Dr. Crum’s tactics of manipulating of Dr. Lile.

18. On March 8, 2020, Dr. Crum told Dr. Lile on the phone that she was chosen to carry his life’s work forward. During this call, Dr. Lile revealed that she was close with Rev. Bernice King, Martin Luther King’s daughter. Dr. Crum, in turn, said that he was also close with Rev. Bernice King and has known her for many years. Dr. Crum frequently highlighted and played up shared connections such as this as a manipulation tactic. For example, Dr. Crum also

highlighted and played up supposed shared connections to the Vatican, to faith, to Mother Theresa, and to the Dalai Lama, as a manipulation tactic to gain Dr. Lile's trust and admiration.

19. Dr. Crum increasingly ingratiated himself with Dr. Lile in the days, weeks, and months to come, acting as a father figure, mentor, and friend.

20. For example, on March 12, 2020, Dr. Crum sent Dr. Lile a lengthy email, which had become his daily practice at this point, attaching one of his articles. In response, Dr. Lile sent Dr. Crum an article she had written when she was a girl. Seizing on the vulnerable moment, Dr. Crum responded, stating that he had been "reading and re-reading [her] youthful Medical Thesis," and going on to state, "the experience that I am about to share with you [is] another coincidence of interest where our paths may have crossed." In that same email, Dr. Crum goes on to describe his "Patent for physiologically synthesized Glutathione," describing it as "highly valued because experts realized it could open wide doors and vast opportunities for the amelioration of Oxidative Stress, and its related etiologies." Dr. Crum attached a valuation report from 2003, highlighting that ProImmune had supposedly been valued, in 2003, in the range of \$1.8 billion to \$5.7 billion, and conservatively at \$2 billion.

21. On April 7, 2020, Dr. Crum's assistant, Naomi, sent Dr. Lile an email with the subject line, "Maverick." The body of that email is below:

Subject: "Maverick"

Laura Lile, M.D., R,PH., Email: DrLaura@LileWellness.com

Dear Dr. Laura,

It seems as if the parallels continue to emerge.

In your letter to Ted Fogarty, you said, "I may need to start calling you 'Maverick' from 'Top Gun.' "

In that declarative sentence, you perceived the "Top Gun" quality that could emerge and is latent in Dr. Ted Fogarty.

There is a parallel here, in that Dr. Crum also saw that latent quality in Dr. Fogarty. It is evident in Dr. Crum's nomination of him to the historic Omaha Central High School Hall of Fame. That nomination letter is attached herewith.

By coincidence or parallel, Dr. Crum's Harvard '57 Class was also labeled by the HMS Administration as the "Maverick Class." The Class was so labeled owing to its brilliant, but oppositional and individual character concerning resistance to participation in any organized response or requests for contributions to Harvard Medical School!

As the permanent Class Agent (like a Class President) Dr. Crum saw the "Top Gun" potential in his Class of '57 and soon thereafter, that Class continually broke all percent giving records set since the founding of the medical school in Year 1782!

You may be interested in that history and the Giving Handbook that Dr. Crum was invited to write for all Class Agents. The Handbook is attached, and it came to be used by many other educational institutions.

These associations were triggered by *your* use of the word "Maverick" and how it underlies your insightful perception of a Maverick's latent energy/brilliance that is waiting to unfold.

Bless you,
Be well.
Best wishes,
Naomi
ProImmune®

22. These are just some of many so-called "coincidences" or "parallels" that Dr. Crum and his cohorts attempted to draw upon and highlight to Dr. Lile.

23. After earning her trust through his manipulating tactics and misrepresentations, Dr. Lile purchased Immune Formulation 200 to provide to her patients.

Dr. Crum Freely Shared His Supposed Knowledge and Information

24. From the first time Dr. Lile spoke to Dr. Crum, he openly shared with her and many others, his so-called knowledge and information. As one of many examples, on March 3, 2020, Dr. Crum sent an email to Dr. Lile and others providing detailed information about his supposed knowledge and understanding of the science behind Immune Formulation 200. The

recipients included individuals who, on information and belief, were under no confidentiality obligations to Dr. Crum or ProImmune, including Darcy Cavanaugh, Alan Ogden, Edward Fogarty, M.D., and Paul Harch, M.D.

25. Similarly, on March 5, 2020, Dr. Crum sent another group email, further detailing the science and information related to Immune Formulation 200. On information and belief, the recipients of the email were not subject to any confidentiality obligations to Dr. Crum or ProImmune; Dr. Crum was freely sharing his supposed knowledge and information related to Immune Formulation 200.

26. An email that Dr. Crum sent on March 21, 2020 to Dr. Lile, Ted Fogarty, M.D., and Leslie Little is yet another example of Dr. Crum freely sharing his supposed knowledge and information related to Immune Formulation 200. That email also included ProImmune's agent Ryan Abbott and attached "four pages that are being compiled for a book I have been commissioned to write by Wiley Publishing Company" related to "Mechanisms of Action or pleiotropic properties that have been identified for Glutathione."

27. On March 22, 2020, Dr. Crum sent another detailed email to Dr. Lile, Dr. Fogarty, Leslie Little, and Ryan Abbott concerning the science behind Immune Formulation 200. On information and belief, Dr. Crum would freely share his supposed scientific knowledge and information in an effort to manipulate and induce others to enter agreements with him. Dr. Crum would regularly advertise and market Immune Formulation 200 and related products as patented products, including by identifying various U.S. patents as covering the products when he knew or should have known they were not covered by any U.S. patent claims.

Dr. Crum Induces Dr. Lile to Enter a Distribution Agreement Via False Representations

28. Seeking to further attach themselves to Dr. Lile's notoriety, ProImmune and Dr. Crum—via false representations—induced Dr. Lile to enter a Distribution Agreement.

29. During the early stages of the relationship, Dr. Crum continually sought to have Dr. Lile deepen her involvement and financial investment with Immune Formulation 200® and in partnering with ProImmune. For instance, ProImmune sought to have Dr. Lile become a spokesperson for the Immune Formulation 200® due to her credibility and reputation in the industry.

30. To that end, Dr. Crum, through personal communications with Dr. Lile and through numerous other means, made numerous false representations to Dr. Lile to induce her to enter the Distribution Agreement.

Dr. Crum Misrepresented that Immune Formulation 200® is Patented

31. Dr. Crum and ProImmune represented to Dr. Lile on numerous occasions and through various means that Immune Formulation 200® is covered by various U.S. Patents, including RE 39734 when, in fact, Dr. Crum and ProImmune had actual knowledge that it is not covered by a U.S. patent.

32. Dr. Crum, his assistant, Naomi, and his attorney, Ryan Abbott, represented to Dr. Lile that Immune Formulation is covered by U.S. Patents. Further, ProImmune's website, as well as the product labels, state the formulation is covered by U.S. Patents.

33. In fact, Dr. Crum, through his verified Complaint has sworn under oath that Immune Formulation 200 is "a patented product" and has alleged in other court filings that the Immune Formulation 200 is a patented product.

34. ProImmune's packaging for the Immune Formulation 200® falsely indicates that it is "PATENTED" by "U.S. Patent RE 39734".



35. ProImmune’s website falsely indicates that the Immune Formulation 200® is “PATENTED” by “U.S. Patent RE 39734”, including in at least by the following statements:

- “Immune Formulation 200® has been issued U.S. Patent RE 39734. The unique properties include the ability to maintain effectiveness under almost any environmental concerns (freeze it, boil it). This stability confers these benefits to any and all food recipes.”¹
- “ProImmune®’s Immune Formulation 200® is the patented composition of amino acids University-proven in in vitro tests to increase bodily Glutathione levels.”²

Dr. Crum developed Immune Formulation 200®:

Title of Invention: Nutritional or Therapeutic Composition to Increase Bodily Glutathione Levels

Patent No.: US 6,592,908 B1

Date of Patent: July 15, 2003

Amendment (11/181,001) filed:

Patent No.: US RE 39734

Date of Patent: July 17, 2007

¹ See https://www.proimmuneco.com/imm_f200/index.html

² See <https://www.proimmuneco.com/index.html>

- Dr. Crum's biography page on the ProImmune website lists his present position as: "President, The ProImmune Company, L.L.C., a company using Dr. Crum's Patent I (US 6,592,908B1) and Patent II (US 6,667,063B2) to create immune-enhanced dietary supplements (Immune Formulation 100™ or Immune Formulation 200®) to increase the intracellular synthesis of Glutathione."³
- And the Commercial Licensing page on the ProImmune website states: "The Patent can help protect your market position."⁴

36. ProImmune's website (<https://www.proimmuneco.com/>) further falsely states the Immune Formulation 200® is covered by U.S. patents, as shown below, for example:



37. Immune Formulation 200 is not, however, covered by any U.S. patent.

³ See <http://www.proimmuneco.com/albert/>

⁴ See <https://www.proimmuneco.com/license/index.html>

38. The prosecution history of RE 39734 makes clear that Immune Formulation 200® is not covered by RE 39734.

39. RE 39734 is a Reissue of U.S. Pat. No. 6,592,908 (the “’908 Patent”), titled “Nutritional or Therapeutic Compositions,” issued on July 15, 2003, listing Dr. Crum as the Inventor.

40. On July 12, 2005, ProImmune and Dr. Crum subjected the ’908 Patent to reexamination via U.S. Patent Application No. 11/181,001, seeking to broaden the claims of the ’908 Patent to cover Immune Formulation 200®. The Patent Office rejected ProImmune’s and Dr. Crum’s attempt to broaden the claim language.

41. On January 6, 2006, the Examiner issued a first rejection, which contained a restriction requirement because the application contained two distinct inventions. The examiner sorted the claims into two groups. Group 1 corresponded with the “[O]riginal Patent Claims + slight modifications as set forth in new claims 32, 34, 36, 38 and 40.” Group 2 corresponded to the “Remaining New Claims.” The Examiner noted “the new claims, which make up Group II, are directed to substantially broader mixture of compounds and completely different proportions and/or amounts.”

42. The examiner found, “[w]ith respect to the precursor compounds or substance in Group II, there is no end to what could be considered ‘derivatives’ of glutamic acid, cystine and glycine, or ‘derivatives of amino acids that can be converted to glutathione.’ Such language reads on *virtually any peptide or protein based supplement or food item.*”

43. Stated differently, the Examiner found that Immune Formulation did not represent a new or novel invention worthy of patent protection.

44. Dr. Crum and ProImmune elected the claims of Group 1, which, as explained above, were much narrower than the claims of Group 2.

45. The claims of Group 1 eventually received a notice of allowance and issued as RE 39,734 on July 17, 2007.

46. The unelected claims of Group 2, which would have covered Immune Formulation 200® if issued, were abandoned and dedicated to the public.

47. Therefore, at least by 2007, Dr. Crum and ProImmune both had actual knowledge that the claims of RE 39,734 did not cover, and could not cover, the Immune Formulation 200®.

48. Despite this, Dr. Crum, ProImmune, and others working at their direction, continue to falsely represent that Immune Formulation 200® is covered by RE 39,734, RE 42,645, and other U.S. patents.

49. As noted above, on March 3, 2020, Dr. Crum emailed Dr. Lile informing her that he had “Express Mailed to you two containers of Immune Formulation 200® packaged for transmittal to the Vatican,” and noting that the label on each container includes the following: US Patent RE42,645E/RE39,734E.

50. On March 11, 2020, Dr. Crum sent a similar email regarding labeling of the product, stating that the label should include US Patent RE42,645E/RE39,734E.

51. On March 15, 2020, Dr. Crum sent Dr. Lile an email regarding a supposed Stress Watcher Kit, stating that it is covered by U.S. Patent 9,229,014 B2.

52. On March 28, 2020, Dr. Crum’s assistant, Naomi, sent Dr. Lile two labels for Immune Formulation, including a Certificate of Authenticity. Both labels identified U.S. Patent RE42645, as shown below.



53. On March 18, in response to Dr. Lile’s Letter of Intent to purchase Immune Formulation, Dr. Crum’s attorney, Ryan Abbott, stated in an email that “Dr. Crum is very excited at the prospect of working with Dr. Lile, and is giving serious consideration to the prospect of having her as an exclusive licensee.” That same day, Dr. Crum emailed Dr. Lile, informing her that purchase orders must go through ProImmune because it is “the Patent holder.”

54. There are numerous other examples of similar misrepresentations related to Immune Formulation being covered by a patent.

Dr. Crum Misrepresented that ProImmune is Worth Billions of Dollars

55. As noted above, on March 15, 2020, Dr. Crum represented to Dr. Lile that ProImmune was valued, in 2003, at between \$1.8 billion and \$5.7 billion, and conservatively at \$2 billion. Dr. Lile repeatedly asked Dr. Crum what ProImmune was valued at in 2020, and in response, Dr. Crum assured Dr. Lile that it was worth billions. On information and belief, Dr. Crum’s representations were false.

56. On multiple additional occasions, Dr. Crum represented to Dr. Lile, both in numerous writings and verbally on numerous occasions, that ProImmune was valued in the billions of dollars.

Dr. Crum Told Dr. Lile that She Would Win the Nobel Prize for Working with Him

57. In furtherance of his self-promotion and attempted manipulation, Dr. Crum represented to Dr. Lile, both in numerous writings and verbally on numerous occasions, that that if she partnered with ProImmune, she was very likely to win the Nobel Prize.

58. Dr. Crum represented to Dr. Lile, both in numerous writings and verbally on numerous occasions, that he had close ties with several Nobel Prize winners and their families, and that he had significant political power that he was ready to use to ensure Dr. Lile received the Nobel Prize.

Dr. Crum Misrepresented ProImmune's Product Delivery Capacity and Capabilities

59. Ryan Abbott is an individual who is heavily involved in Dr. Crum's business, the patent prosecution work mentioned above and has had numerous dealings with Dr. Lile as an employee or agent of ProImmune.

60. On March 28, Ryan Abbott, in response to Dr. Lile's Letter of Intent, informed Dr. Lile by email that ProImmune had the ability to deliver a 17,000 kg order in six weeks. Ryan Abbott stated, "[t]he standard turnaround time for production is up to 6 weeks," and if "Dr. Lile is prepared to commit to the 20,000 kg order now, and place the deposit this week, we should be able to arrange for 17,000 kg to be produced within 6 weeks." (emphasis added). Dr. Lile committed to the 20,000 kg order and placed the deposit within the time required. Nevertheless, the order took more than fourteen weeks and there were numerous problems with it.

61. On information and belief, Dr. Crum and ProImmune were aware of the production times and substantial delivery issues. For example, on February 12, 2020,

ProImmune sued another distributor, Holista, for breach of a distribution agreement. Holista filed counterclaims against ProImmune, and Holista witnesses in that lawsuit have testified under oath that every single shipment from ProImmune arrived in broken packaging, wet, and dirty. Dr. Lile and Three Aminos encountered identical or nearly identical issues with the shipments of products from ProImmune.

Dr. Lile Reasonably Relied on Dr. Crum's and ProImmune's Representations in Entering the Distribution Agreement

62. Dr. Lile and Three Aminos reasonably relied on the above representations and were led to believe, among other things, that Immune Formulation 200® was covered by patents, that Dr. Crum wanted her to carry his supposed life's work forward, that ProImmune was worth billions of dollars, that Dr. Crum shared Dr. Lile's devout faith, and that ProImmune had the capability and capacity to meet her product delivery needs. Most importantly, Dr. Lile was led to believe that if she wanted to distribute Immune Formulation 200®, she had to acquire it from Dr. Crum and/or ProImmune because it was covered by their patents.

63. Reasonably relying on these representations, on or around April 24, 2020, Three Aminos was induced into entering a Distribution Agreement with ProImmune, under which Three Aminos agreed to distribute ProImmune's Immune Formulation 200® product.

ProImmune and Dr. Crum Breach the Distribution Agreement and Warranties Therein

64. After Dr. Crum and ProImmune induced Dr. Lile to enter the Distribution Agreement based on the material misrepresentations discussed above, Counterclaim-Defendants turned around and breached the Agreement, including material warranties made therein.

65. For instance, Section 9.1.2 of the Distribution Agreement warrants that the "the information provided by ProImmune to Distributor in writing regarding the Product, or use thereof," including "the information available on ProImmune's website . . . is accurate, correct, and complete in all material respects." Despite this warranty and as explained above,

ProImmune's written statements to Dr. Lile and ProImmune's website represents that Immune Formulation is covered by U.S. patents. That is false.

66. Further, Section 9.1.1.2 of the Distribution Agreement warrants that the Immune Formulation 200 supplied by ProImmune to Three Aminos "is of satisfactory quality, free of residuals and contaminants, and fit in all respects [f]or the purpose(s) for which the Product is intended and shall comply with all and any specifications provided by ProImmune for such Product." Despite this warranty, the Product did not comply with the specifications provided by ProImmune because, for example, it was not covered by any U.S. patents. Further, the Product failed to comply with the specifications provided by ProImmune because it was delivered in damages containers.

67. Section 9.1.1.3 of the Distribution Agreement warrants that the Immune Formulation 200 supplied by ProImmune to Three Aminos "conforms to the ingredient of such Product as described on the label, package inserts and packaging; and in all respects suitable for distribution or retailing to the customer in compliance with applicable laws, regulations and administrative requirements in the United States." Despite this warranty, the Product did not conform with the Product's label, package inserts and/or packaging because, for example, the labels, package inserts and/or packaging identified the Product as being covered by U.S. patents. That was false.

68. Section 10.1.2 of the Distribution Agreement provides that ProImmune warrants that "it has full legal rights to use the Patents and Trade Secrets employed in the manufacture of the Product in the United States." That is false. Despite warranting that the information on ProImmune's website was accurate, and despite ProImmune's website stating that Immune Formulation is covered by U.S. patents, it is not covered by any such patents.

69. Moreover, even if the U.S. patents identified on ProImmune’s website covered the Immune Formulation product, ProImmune did not have “full legal rights” to the identified patents at the time the parties entered the Distribution Agreement. As evidenced by the U.S. Patent & Trademark Office’s website, Dr. Crum did not assign the relevant patents to ProImmune until March 15, 2022, nearly two years after the purported Distribution Agreement was executed.

Dr. Crum Induces Dr. Lile to Enter a Joint Venture Via Misrepresentations

70. Simultaneous with his efforts to induce Dr. Lile to enter the Distribution Agreement, Dr. Crum made false representations to induce Dr. Lile to enter further agreements and a joint venture with ProImmune and Dr. Crum.

71. As noted above, on March 15, 2020, Dr. Crum told Dr. Lile about his supposed Stress Watchers Kit, stating in an email, “it would take almost 12 years and enormous cost to go through the rigors of the Patent Office and up to its ultimate Patent Office ‘Supreme Court’ and—finally—a Triumph! Twelve years later after a vast cost to/for Patent Attorneys, the Patent Office Supreme Court issued a unanimous approval of this Patent: ‘Method of Assessing the Need for and the Effectiveness of Therapy with Antioxidants’ US 9,229,014 B2.”

72. In that same email, Dr. Crum represented that ProImmune was worth billions of dollars. On information and belief, that statement was false, and Dr. Crum knew or should have known of its falsity.

73. On April 4, 2020, Dr. Crum sent Dr. Lile an email detailing the science of Immune Formulation 200 and so-called “Packet Potential” as a follow-up to a discussion Dr. Crum and Dr. Lile recently had on a call. Specifically, on that call, Dr. Crum explained a so-called Packet Potential opportunity. Dr. Crum said that he would be willing to license the packet opportunity to Dr. Lile.

74. In the April 4 email, Dr. Crum again misrepresented that ProImmune was worth billions of dollars. Dr. Crum also states, “The data in this chronology suggests that Nrf2 may have a participatory and pivotal role in your antiviral compilation via Glutathione synthesis. Per such unique role, it happens also to offer a ‘one-of-a-kind’ marketing opportunity. This data is a follow-up of the discussion yesterday, and it is related to the Discovery/Chronology of Nrf2 and the Important Activation of Nrf2 by Immune Formulation 200® (F1)* with its disulfide bond (a biomarker of Oxidative Stress) that can signal the genome in High-Fat-Diet Subjects. A review of its scientific significance is relevant and is related to the Statin Patent Application and other Mechanisms of Action market. Per your further marketing assistance, the interrelationship between Immune Formulation 200®, Nrf2, and Lipid Metabolism is of enormous commercial and scientific value. . . . NOTE: In these presentations, the following interchangeable terms are used in University Research and in peer-reviewed scientific articles: Patent RE 42,645E/RE39,734, Immune Formulation 200® or ‘F1’ or ‘FT061452.’ In peer-reviewed scientific articles, ‘F1’ is the term most often used referring to Immune Formulation 200® based on Patent RE42,645E/RE39,734. Immune Formulation 200® is also known as VITAMIN GSH-S® and both refer to the formulation based on Patent.”

75. The email goes on to discuss the science behind his so-called discoveries and the supposed value in so-called packets. Dr. Crum stated that, “Pharma has long searched for toxins to activate Nrf2 [and] Pharmaceutical companies had invested literally hundreds of millions of dollars in order to discover an activator of gene Nrf2.” However, according to Dr. Crum, “Patent RE42,645E—physiologically and with no side effects—activates the very gene that pharma had invested hundreds of millions of dollars to achieve with highly toxic synthetic drugs.” (Emphasis in original).

76. Dr. Crum further states that “After the medical school consortium determined via extensive research comparative studies that Immune Formulation 200® proved superior to NAC (the pharma standard), they invested \$25,000,000.00 of their NIH and other funds for research into Immune Formulation 200® (Patent RE39,734 and RE42,645E). In a major and unexpected addition, F1 was also found to activate the valuable Nrf2 immune gene in High Fat Diet (HFD) test subjects by promoting translocation of Nrf2 into the cell’s nucleus! That unexpected scientific development was reported to being like ‘batting the ball out of the park.’ (Emphasis in original).”

77. Dr. Crum also states that “REATA had sold certain sales rights for hundreds of millions of dollars to Abbott Laboratories (**\$450 million, actually**), based on the ability of its Bardoxolone Methyl to activate Nrf2,” an ability that Dr. Crum asserted he had discovered in his purported patents related to Immune Formulation 200. (Emphasis in original).

78. Dr. Crum makes numerous additional statements regarding the importance and value of Patent RE 42,645E and Immune Formulation 200, calling them a “Game Changer.” He also states that, “The basic reason that I was invited by Dr. Paul Talalay to make a presentation at the Johns Hopkins Medical School was because 1) Patent RE42,645E not only physiologically synthesizes and replenishes bodily levels of Glutathione, but 2) because RE42,645E also physiologically activates or maintains and promotes translocation of the valuable immune gene Nrf2 into the cell nucleus in HFD subjects.” (Emphasis in original).

79. In closing, Dr. Crum states, “In reviewing the above items, you may more readily see why the physiological activation of Nrf2 by Immune Formulation 200® has excited world-renowned scientists at the distinguished West Coast medical schools, Their life work revolves around a search to alleviate acute or unmanageable immune crises. Immune Formulation 200® came under their investigation via physiologically synthesized Glutathione (Patent RE42,645E)

and the benefits it can have in the therapeutic armamentarium of innate immunity Low Glutathione levels are related to at least **98** illnesses/medical conditions as documented in over **115,000** research articles in scientific journals (Attachment **15A**). However, ProImmune's unique synthesis is via the natural precursor method of physiological production. . . . Thank you for your dedicated and insightful scientific, Health and commercial interest. Could you have ever imagined when you brought the name "Three Aminos" together, with its disulfide bond of L-Cystine, the vast pleiotropy of possibilities that were being activated." (Emphasis in original).

80. Dr. Crum attached to the email "Two Patent Valuations before the Immune Formulation 200@/NRF2 activation discovery." (Emphasis in original). This is a further example of Dr. Crum's misrepresentations regarding the purported value of ProImmune and Immune Formulation 200.

81. On information and belief, the statements in this letter were false and misleading, and Dr. Crum knew or should have known of their falsity.

82. Around this time, Dr. Crum insisted that Dr. Lile read the book, "Sweet and Low: A Family Story," by Rich Cohen. In discussing the book with Dr. Lile, Dr. Crum represented that he knows the family that owns Sweet and Low, that he had been to the Sweet and Low plant, and that there was an opportunity, if Dr. Lile was interested, to make billions of dollars by incorporating Immune Formulation into a sugar packet.

83. Dr. Crum sent Dr. Lile numerous other emails, documents, and materials designed to mislead Dr. Lile into reasonably believing that ProImmune and its patents and intellectual property were worth billions of dollars.

84. Along the same lines and as noted above, Dr. Crum represented to Dr. Lile on numerous occasions that if she partnered with ProImmune, she was very likely to win the Nobel Prize.

85. Dr. Crum further represented that to sell Immune Formulation 200® for COVID-19 (Prothione) and for lipids (Lipinol), Dr. Lile also had to obtain a license for U.S. Patent No. 9,229,014. Dr. Crum insisted that all the patents that supposedly covered Immune Formulation 200® had to be licensed together.

86. Dr. Lile continued to reasonably rely on Dr. Crum's representations and, on November 7, 2020, she was induced into entering a series of agreements based entirely on those representations. Those agreements are attached to the Complaint as Exhibits 1 (Oxidative Stress Kit Commercialization Agreement), 2 (Pharmaceutical Commercialization Agreement), 3 (Operating Agreement of Innate FFAAP Medicine LLC), 4 (COVID-19 Pharmaceutical License Agreement), and 5 (Dyslipidemia Pharmaceutical License Agreement) (collectively, the "Commercialization, License, and Operating Agreements").

Dr. Crum and ProImmune Breached the Commercialization, License, and Operating Agreements

87. Counterclaim-Defendants breached the purported Commercialization, License, and Operating Agreements, and the express and implied warranties therein.

88. First, Counterclaim-Defendants breached the Oxidative Stress Kit Commercialization Agreement. Section 2.1 of that agreement provides that the parties, ProImmune and Three Aminos, would "create a new limited liability company ('Company')" that would be owned in equal percentages regardless of the amount of capital or other contributions made by the parties. The newly founded company is Plaintiff Innate.

89. The only purported consideration required by ProImmune under the Oxidative Stress Kit Commercialization Agreement was to "assign and transfer the Intellectual Property Rights to the [newly founded] Company." *See* Exhibit 1 at Section 3.1.

90. Three Aminos, on the other hand, was required to "pay \$5 million in nonrefundable funds to ProImmune." *See id.* at Section 3.2. Three Aminos was also "obligated

to fund Digitization by lending [the new] Company up to . . . \$1 million” for development costs of the supposed Oxidative Stress Kit. *See id.* at Section 3.3. Three Aminos was also required “to provide up to, but no more than \$1 million in each calendar year to the Company to fund Company costs, expenses, and operations.” *See id.* at Section 3.4.

91. The Agreement warrants that ProImmune “is the sole and exclusive owner of the entire right, title, and interest in and to the Intellectual Property Rights.” *See id.* at Section 7.1.1.

92. The Agreement warrants that ProImmune “has not granted, and is not under any obligation to grant, to any third party any license, lien, option, encumbrance, or other contingent or non-contingent right, title, or interest in or to the Intellectual Property Rights that conflicts with the rights granted to the Company.” *See id.* at Section 7.1.3.

93. Introductory clauses in the Agreement state, “ProImmune is the owner of various property rights associated with Immune Formulation 200® and related products,” and “ProImmune has developed a patented oxidative stress test kit and associated intellectual property for measuring oxidative stress.” The Agreement defines “Intellectual Property Rights” as “all relevant industrial and other intellectual property rights owned or controlled by ProImmune which exclusively protect the Oxidative Stress Kit, primarily consisting of the patent family associated with US Patent Number 9,229,014 titled “Methods of accessing the need for and the effectiveness of therapy with antioxidants” (‘Patents’), and also comprising associated know-how.” And the Oxidative Stress Kit is defined as “the patented test kit developed by ProImmune for measuring oxidative stress.”

94. Upon entering the Agreement, Counterclaim-Defendants knew that they would be in breach of at least the warranties provided in Sections 7.1.1 and 7.1.3, and they did breach those warranties upon entering the Agreement. Specifically, Counterclaim-Defendants breached the warranties of Section 7.1.1 because, upon information and belief, there were no Intellectual

Property Rights for ProImmune to license related to the Oxidative Stress Kit. That is, on information and belief, US Patent Number 9,229,014 does not cover the purported Oxidative Stress Kit, and neither Dr. Crum nor ProImmune owned or controlled any purported know-how related to the Stress Kit. As described above, Dr. Crum is freely sharing of his scientific findings.

95. Counterclaim-Defendants breached the warranties of Section 7.1.3 because, on information and belief, Counterclaim-Defendants have granted, or are under obligations to grant, to third parties licenses, liens, options, encumbrances, or other contingent or non-contingent rights, titles, or interests in or to the Intellectual Property Rights that conflicts with the rights, if any, granted to the Company,

96. Second, Counterclaim-Defendants breached the Pharmaceutical Commercialization Agreement (“PCA”).

97. Section 9.1 of the PCA states that all parties agree to deal with each other honestly and in good faith. Counterclaim-Defendants failed to meet this obligation including through the numerous misrepresentations discussed above, and specifically through his misrepresentations that Immune Formulation 200 is covered by a patent.

98. Counterclaim-Defendants have also breached Section 9.1 of the PCA due to Dr. Crum’s failure to take Dr. Lile’s phone calls or respond to emails since May 2022.

99. Third, Counterclaim-Defendants breached the Operating Agreement. That Agreement provides that ProImmune shall license to the Company pursuant to the COVID-19 Pharmaceutical License Agreement and the Dyslipidemia Pharmaceutical Agreement. Sections 3.1 of each of those Agreements provides for an Exclusive License under the Licensed Patents to make use and sell the Licensed Products. Licensed Products is defined as including Immune Formulation. Counterclaim-Defendants are therefore misrepresenting that Immune Formulation

200 as a Licensed Product, requires a license to the Licensed Patents, when Immune Formulation 200 is not protected by a patent or trade secret.

100. Fourth, Counterclaim-Defendants breached the COVID-19 and Dyslipidemia Pharmaceutical License Agreements. For example, assuming Immune Formulation 200 is covered by some protectable intellectual property interest provided for in the License Agreements (it is not), whether a U.S. patent or trade secret, part of the License Agreements, then Counterclaim-Defendants have breached Section 14.5(a). That Section warrants that ProImmune is not aware of anything that prohibits its ability to license the Licensed Products. ProImmune, however, had actual knowledge that at least under the Distribution Agreement, Three Aminos was a distributor of Immune Formulation 200 and therefore could not have granted an exclusive license to the Company to make, use and sell, the Licensed Products under the Licensed Patents, because Three Aminos already possessed that right. Additionally, ProImmune continues to offer licensing opportunities to Immune Formulation 200 through its website. Therefore, it is necessary to determine if Immune Formulation is covered by any of the Licensed Patents.

101. Despite ProImmune agreeing, on November 7, 2020, to assign and transfer the Intellectual Property Rights to the various joint ventures, on information and belief, when the agreements were executed, ProImmune did not have title to assign the patent. According to the USPTO's website, Dr. Crum did not assign the '014 patent to ProImmune until March 2, 2021. Dr. Crum and ProImmune therefore breached the warranties.

The Agreements are Invalid for Lack of Consideration

102. The Commercialization, License, and Operating Agreements are invalid and unenforceable because ProImmune did not provide any consideration. The agreements are illusory because they impose significant obligations on Dr. Lile but none on Dr. Crum. As

described above, the Pharmaceutical Agreements require that Three Aminos fund the joint ventures and conduct, among other things, all the necessary clinical trials and filings to seek FDA approval. At the same time, the Pharmaceutical Agreements provide that they may be terminated at Dr. Crum's discretion and do not impose any substantial obligations on Dr. Crum or ProImmune. And, moreover, the license provides nothing by way of Immune Formulation 200 because none of the defined Intellectual Property Rights protect Immune Formulation 200 in any way.

Dr. Crum Steals Trade Secrets and Files a Patent Application

103. Dr. Lile conducted several studies in Rwanda related to Immune Formulation 200. Dr. Lile confidentially shared her clinical trial data and updates from those studies with Dr. Crum, including a clinical trial was for treating COVID-19, which included patients that were positive for HIV. The results of the study showed that the product appeared to reduce viral load in HIV positive patients.

104. Dr. Lile shared this information as part of her work under the various agreements described above, each of which contain a confidentiality provision.

105. Equipped with Dr. Lile's proprietary data and trade secrets, Dr. Crum secretly filed a provisional patent application, naming himself as the sole inventor and naming ProImmune as the owner/assignee.

106. After secretly filing the provisional patent application for treating HIV, Dr. Crum contacted Dr. Lile and offered to allow Dr. Lile, through Innate and/or Prothione, to pursue treatment for HIV if she paid Dr. Crum \$2 million to license his patent based on Dr. Lile's research.

107. Section 1.15 of the Pharmaceutical Commercialization Agreement defines "Three Aminos Intellectual Property Rights" as "all industrial and other intellectual property rights, now

or in the future, owned or controlled by Three Aminos exclusively related to, or necessary for the development or marketing of, the Formulations comprising or relating to: (a) Patents; . . . (d) works of authorship, filings, studies and data prepared or developed by Three Aminos before or following the Effective Date and including without limitation related to all FDA filings (INDs, NDAs, etc.) and Phase III Clinical Trials[;] . . . (e) Trade Secrets; (f) formulas, compounds, preparations, components and know-how.”

108. Dr. Lile and Three Aminos therefore, by its terms, owned the intellectual property rights arising from, among other things, the clinical trials that were conducted in Rwanda.

109. Notwithstanding Counterclaimants’ intellectual property rights, Dr. Crum and ProImmune misappropriated those rights.

COUNT ONE

Declaratory Judgment of Patent Invalidity Under 28 U.S.C. § 2201

110. Counterclaimants reallege and incorporate the foregoing Paragraphs of their Counterclaims as fully set forth herein.

111. ProImmune has brought suit against Counterclaimants for breach of contract and breach of fiduciary duties arising from certain contracts. By alleging that Counterclaimants breached these contracts and/or fiduciary duties, ProImmune is necessarily alleging that the patents in its portfolio, U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734, are valid because a potential future license to such patents are the only purported consideration in the agreements at issue. Counterclaimants deny that the patents are valid or enforceable. There is therefore a substantial, actual, and continuing controversy between ProImmune and Counterclaimants as to the validity and enforceability of U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734.

112. As described above, Dr. Crum repeatedly represented to Dr. Lile that Immune Formulation 200 was covered by U.S. patents and that Dr. Lile needed a license to the patent

portfolio to license the product. Further, in inducing Dr. Lile to enter unenforceable agreements, Dr. Crum offered potential future licenses to the patent portfolio as the consideration.

113. ProImmune's patents, including U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734, do not cover Immune Formulation 200. As such, Counterclaimants do not need a license to sell Immune Formulation 200 or to utilize it in research.

114. For this additional reason there is therefore a substantial, actual, and continuing controversy between Counterclaimants and ProImmune. If Counterclaimants attempt to sell Immune Formulation 200 without a license, and/or if Counterclaimants make products that utilize Immune Formulation 200, ProImmune and Dr. Crum will assert additional breach of contract claims against Counterclaimants as well as patent infringement claims.

115. Further, Counterclaimants assert breach of contract claims against Counterclaim-Defendants below. The basis of these claims, in part, rests on Counterclaim-Defendants' representations and warranties that the various U.S. Patents cover Immune Formulation 200. Unless Counterclaim-Defendants admit they have breached the representations and warranties, then ProImmune is necessarily alleging that the patents in its portfolio, U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734, are valid and enforceable. Counterclaimants deny that the patents are valid or enforceable. There is therefore a substantial, actual, and continuing controversy between Counterclaim-Defendants and Counterclaimants as to the validity and enforceability of U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734

116. Counterclaimants therefore seek a declaratory judgment that each claim of U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734 are invalid or void for failing to satisfy one or more of the conditions for patentability set forth in Part II of Title 35 of the United States Code, including, but not limited to §§ 101, 102, 103, and/or 112.

117. U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734 further fail to inform, with reasonable certainty, those skilled in the art about the scope of the purported inventions.

118. Counterclaimants are entitled to a judgment that U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734 are invalid.

119. Counterclaimants are entitled to a judgment that U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734 are unenforceable due to ProImmune's and Dr. Crum's inequitable conduct on the Patent Office, as well as their past and continuing patent misuse.

120. This matter is an exceptional case within the meaning of 35 U.S.C. § 285.

COUNT TWO

Declaratory Judgment that no patent covers Immune Formulation 200

121. Counterclaimants reallege and incorporate the foregoing Paragraphs of their Counterclaims as fully set forth herein.

122. ProImmune has brought suit against Counterclaimants for breach of contract and breach of fiduciary duties arising from certain contracts. By alleging that Counterclaimants breached these contracts and/or fiduciary duties, ProImmune is necessarily alleging that the patents in its portfolio, U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734, cover Immune Formulation 200 and related products described in the agreements. This is necessarily the case because the only purported consideration on the part of ProImmune to support enforcing these contracts is a license to such patents. Counterclaimants deny that a license to the patents qualifies as consideration sufficient to render the agreements enforceable. There is therefore a substantial, actual, and continuing controversy between ProImmune and Counterclaimants as to the scope of the claims in at least U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734.

123. As described above, Dr. Crum repeatedly represented to Dr. Lile that Immune Formulation 200 was covered by U.S. patents and that Dr. Lile needed a license to the patent

portfolio to license the product. Further, in inducing Dr. Lile to enter unenforceable agreements, Dr. Crum offered potential future licenses to the patent portfolio as the consideration.

124. On information and belief, ProImmune's patents, including U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734, do not cover Immune Formulation 200. As such, Counterclaimants do not need a license to sell Immune Formulation 200 and any statement made by ProImmune or Dr. Crum that Immune Formulation 200 is a patented product is therefore false.

125. As noted below, Counterclaim-Defendants have breached numerous agreements by representing that Immune Formulation 200 is covered by ProImmune patent, when it is not.

126. Counterclaimants therefore seek a declaratory judgment that no claim of U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734 cover any product described in the agreements, including but not limited to Immune Formulation 200.

127. Because Counterclaim-Defendants believe that Immune Formulation 200 is covered by a ProImmune patent, including U.S. Patent Nos. 9,229,014, RE42,645, or RE39,734, genuine dispute exists between the parties as to whether or not Immune Formulation 200 is protected by a valid U.S. Patent and that determination is material to the disputes asserted herein.

128. This dispute affects the rights and obligations of the parties to make, use or sell the same or similar formula as Immune Formulation 200, as well as the rights and obligations of the parties under the various agreements as set forth above.

129. Accordingly, this Court should issue a declaration that the formula used to make Immune Formulation 200 is not covered by any valid U.S. Patent, including but not limited to U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734.

COUNT THREE

Misappropriation of Trade Secrets Under the Defend Trade Secrets Act – 18 U.S.C. § 1836(b)(1) (Against Dr. Crum, and ProImmune)

130. Counterclaimants reallege and incorporate the foregoing Paragraphs of their Counterclaims as fully set forth herein.

131. Dr. Lile's Trade Secrets were developed at a great expense and were the result of years of research, testing, and development. Dr. Lile keeps and has kept her Trade Secrets confidential. Dr. Lile's Trade Secrets are not generally known in the industry or to the public.

132. As Dr. Lile's business partner and through their explicit and/or implicit contractual relationships, Dr. Crum had access to Dr. Lile's confidential and proprietary trade secret information.

133. Dr. Lile's Trade Secrets are used in or intended for use in interstate commerce.

134. Dr. Lile has taken reasonable steps as part of her ongoing operations to maintain the confidential nature of her Trade Secrets. For example, Dr. Lile has limited access to her confidential information to only Dr. Crum and those persons that work on the technology and are under an express or implied obligation to maintain its secrecy. Moreover, the Distribution Agreement, Commercialization, License, and Operating Agreements include confidentiality provisions, and therefore Counterclaim Defendants are obligated to maintain the confidential nature of Dr. Lile's Trade Secrets. *See, e.g.*, Exhibit 1 at Section 6 and Exhibit 2 at Section 4.

135. Based on Dr. Crum's filing of at least U.S. Patent Application No. 63/239,341, Dr. Crum and Abbott are alleged to have used and are believed to be continuing to use Dr. Lile's Trade Secrets without authorization, authority, consent, or permission, including but not limited to their personal capacity as well as through or otherwise in conjunction with ProImmune or one or more entities owned or controlled by Dr. Crum. It is believed that Dr. Crum and Abbott are filing other patent applications that rely on and/or disclose Dr. Lile's Trade Secrets. These patent applications are being filed in Dr. Crum's name and he is identifying those applications as his own, as the sole inventor, or as belonging to him or one of the entities he owns or controls.

136. Abbott is the patent attorney that filed at least U.S. Patent Application No. 63/239,341. Based on information and belief, Abbott filed this and other patent applications using Dr. Lile's Trade Secrets when through his work as an employee or agent of ProImmune, he knew or should have known that Dr. Cum and/or ProImmune did not own the data used as the basis for the patent application and therefore misappropriated the information from Dr. Lile.

137. Dr. Crum and ProImmune are maliciously and willfully using misappropriated confidential, proprietary, and trade secret information to their own advantage. Their actions are causing Dr. Lile damage in the marketplace and, upon information and belief, a loss of customers and revenue.

138. Dr. Crum and Abbott both acquired Dr. Lile's confidential, proprietary, and trade secret information by improper means, including taking such information from Dr. Lile without her authorization or consent and filing patent applications using that information to try and procure intellectual property rights owned by Dr. Lile.

139. As a result of Dr. Crum's and Abbott's misappropriation and use of the confidential, proprietary, and trade secret information, Dr. Crum and Abbott have violated the Defend Trade Secrets Act, 18 U.S.C. § 1836(b)(1).

140. As a direct and proximate result of Dr. Crum's violations of the Defend Trade Secrets Act, Dr. Lile has sustained and will continue to sustain damages in an amount to be proven at trial. For example, on information and belief, Dr. Lile has lost, or is foreseeably likely to lose, intellectual property rights in the treatment of HIV based on the clinical research developed by Dr. Lile. As such, she stands to lose significant revenue including, but not limited to the loss of potential customers and patients. Dr. Lile has therefore suffered irreparable harm and is entitled to injunctive relief including, among other things, an assignment of any patent

applications that Dr. Crum has filed related to Dr. Lile's Trade Secrets from Dr. Crum or ProImmune to Three Aminos or Dr. Lile.

141. Dr. Crum's and ProImmune's actions in converting and misappropriating Dr. Lile's confidential, proprietary, and trade secret information for their own gains were willful, wanton, and malicious, and were taken with reckless disregard for Dr. Lile's rights.

142. Legal or monetary remedies are no longer be sufficient. For example, if successful in obtaining patent protection, Dr. Crum and ProImmune, could possibly preclude Dr. Lile from utilizing her research and developing further HIV treatments.

143. Additionally, the development of such HIV treatment would be wrongfully attributed to Dr. Crum and ProImmune withing the medical and scientific community, thereby depriving Dr. Lile of her rightful recognition as the developer of the HIV treatments.

144. These actions would cause and are causing irreparable damage to Dr. Lile in the marketplace, including, but not limited to, damage to Dr. Lile's reputation with current and prospective customers and peers.

145. The egregiousness of Dr. Crum's and Abbott's acts require injunctive relief subject to a determination of the extent the actual or threatened illicit conduct of Dr. Crum and Abbott has caused and will continue to cause Dr. Lile irreparable harm.

COUNT FOUR
Misappropriation of Trade Secrets Under New York Common Law (Against Dr. Crum and ProImmune)

146. Counterclaimants reallege and incorporate the foregoing Paragraphs of their Counterclaims as fully set forth herein.

147. Dr. Lile's Trade Secrets were developed at a great expense and were the result of years of research, testing, and development. Dr. Lile keeps and has kept her Trade Secrets confidential. Dr. Lile's Trade Secrets are not generally known in the industry or to the public.

148. As Dr. Lile's business partner and through their explicit and/or implicit contractual relationships, Dr. Crum had access to Dr. Lile's confidential and proprietary trade secret information.

149. Dr. Lile's Trade Secrets are used in or intended for use in interstate commerce.

150. Dr. Lile has taken reasonable steps as part of her ongoing operations to maintain the confidential nature of her Trade Secrets. For example, Dr. Lile has limited access to her confidential information to only Dr. Crum and those persons that work on the technology and are under an express or implied obligation to maintain its secrecy.

151. Based on Dr. Crum's filing of at least U.S. Patent Application No. 63/239,341, Dr. Crum and Abbott are alleged to have used and are believed to be continuing to use Dr. Lile's Trade Secrets without authorization, authority, consent, or permission, including but not limited to their personal capacity as well as through or otherwise in conjunction with ProImmune or one or more entities owned or controlled by Dr. Crum. It is believed that Dr. Crum and Abbott are filing other patent applications that rely on and/or disclose Dr. Lile's Trade Secrets. These patent applications are being filed in Dr. Crum's name and that he is identifying those applications as his own, as the sole inventor, or as belonging to him or one of the entities he owns or controls.

152. Abbott is the patent attorney that filed at least U.S. Patent Application No. 63/239,341. Based on information and belief, Abbott filed this and other patent applications using Dr. Lile's trade secrets when he knew or should have known that Dr. Cum and/or Abbott misappropriated the information from Dr. Lile.

153. Dr. Crum and ProImmune are maliciously and willfully using misappropriated confidential, proprietary, and trade secret information to their own advantage. Their actions are

causing Dr. Lile damage in the marketplace and, upon information and belief, a loss of customers, revenue and causing reputational damage.

154. Dr. Crum and ProImmune both acquired Dr. Lile's confidential, proprietary, and trade secret information by improper means, including taking such information from Dr. Lile without her authorization or consent and filing patent applications using that information without naming Dr. Lile as an inventor.

155. As a result of Dr. Crum's and ProImmune's misappropriation and use of the confidential, proprietary, and trade secret information, Dr. Crum and Abbott have violated New York common law.

156. As noted above, as a direct and proximate result of Dr. Crum's and ProImmune's misappropriation of these trade secrets, Dr. Lile has sustained and will continue to sustain damages in the form of lost customers, patients and revenues, in an amount to be proven at trial.

157. Dr. Crum's and ProImmune's actions in converting and misappropriating Dr. Lile's confidential, proprietary, and trade secret information for their own gains were willful, wanton, and malicious, and were taken with reckless disregard for Dr. Lile's rights.

158. As noted above, Dr. Lile stands to lose her intellectual property rights as well as reputational and business prestige. Legal or monetary remedies are therefore not sufficient to prevent irreparable harm.

COUNT FIVE

Fraud

159. Three Aminos and Dr. Lile reallege and incorporate the foregoing Paragraphs of their Counterclaims as fully set forth herein.

160. Prior to entering the Distribution Agreement on April 24, 2020, ProImmune through its statements, packaging, and website, among numerous other ways, represented that Immune Formulation 200 was patented by RE 39734 and other U.S. patents.

161. In order to induce Three Aminos to enter the Distribution Agreement and Commercialization, License, and Operating Agreements, ProImmune again represented that Immune Formulation 200 was a patented product. ProImmune in fact warranted in the Distribution Agreement and Commercialization, License, and Operating Agreements that Immune Formulation 200 is covered by U.S. patents. Dr. Crum also sent a written letter to Pope Francis, through Dr. Lile, which represented that Immune Formulation 200 is covered by U.S. patents.

162. Prior to entering the Distribution Agreement as well as before entering the Second Amended Distribution Agreement and the Commercialization, License, and Operating Agreements, Counterclaim-Defendants knew that Immune Formulation 200 was not covered by any U.S. patents.

163. These misrepresentations and/or omissions were made intentionally to induce Three Aminos to enter into the Distribution Agreement, the Second Amendment to the Distribution Agreement, and the Commercialization, License, and Operating Agreements.

164. ProImmune knew at the time that it could not provide the assurance warranted in the Agreements, or such assurances were made with reckless disregard for whether or not they were true.

165. Three Aminos and Dr. Lile reasonably relied on the warranties and promises in the Agreements and entered them to their detriment.

166. Three Aminos and Dr. Lile have suffered damages as a result of these misrepresentations and omissions.

167. Three Aminos and Dr. Lile respectfully request a final judgment against ProImmune for damages in an amount to be determined at trial.

COUNT SIX

Breach of Contract

168. Three Aminos and Dr. Lile reallege and incorporate the foregoing Paragraphs of their Counterclaims as fully set forth herein.

169. Counterclaim-Defendants breached the Oxidative Stress Kit Commercialization Agreement. Section 2.1 of that agreement provides that the parties, ProImmune and Three Aminos, would “create a new limited liability company (‘Company’)” that would be owned in equal percentages regardless of the amount of capital or other contributions made by the parties. The newly founded company is Innate.

170. The only purported consideration required by ProImmune under the Oxidative Stress Kit Commercialization Agreement was to “assign and transfer the Intellectual Property Rights to the [newly founded] Company.” *See* Exhibit 1 at Section 3.1.

171. Three Aminos, on the other hand, was required to “pay \$5 million in nonrefundable funds to ProImmune.” *See id.* at Section 3.2. Three Aminos was also “obligated to fund Digitization by lending [the new] Company up to . . . \$1 million” for development costs of the supposed Oxidative Stress Kit. *See id.* at Section 3.3. Three Aminos was also required “to provide up to, but no more than \$1 million in each calendar year to the Company to fund Company costs, expenses, and operations.” *See id.* at Section 3.4.

172. The Agreement warrants that ProImmune “is the sole and exclusive owner of the entire right, title, and interest in and to the Intellectual Property Rights.” *See id.* at Section 7.1.1.

173. The Agreement warrants that ProImmune “has not granted, and is not under any obligation to grant, to any third party any license, lien, option, encumbrance, or other contingent

or non-contingent right, title, or interest in or to the Intellectual Property Rights that conflicts with the rights granted to the Company.” *See id.* at Section 7.1.3.

174. Introductory clauses in the Agreement state, “ProImmune is the owner of various property rights associated with Immune Formulation 200® and related products,” and “ProImmune has developed a patented oxidative stress test kit and associated intellectual property for measuring oxidative stress.” The Agreement defines “Intellectual Property Rights” as “all relevant industrial and other intellectual property rights owned or controlled by ProImmune which exclusively protect the Oxidative Stress Kit, primarily consisting of the patent family associated with US Patent Number 9,229,014 titled “Methods of accessing the need for and the effectiveness of therapy with antioxidants” (‘Patents’), and also comprising associated know-how.” And the Oxidative Stress Kit is defined as “the patented test kit developed by ProImmune for measuring oxidative stress.”

175. Upon entering the Agreement, Counterclaim-Defendants knew that they would be in breach of at least the warranties provided in Sections 7.1.1 and 7.1.3, and they did breach those warranties upon entering the Agreement. Specifically, Counterclaim-Defendants breached the warranties of Section 7.1.1 because there were no Intellectual Property Rights for ProImmune to license related to the Oxidative Stress Kit. That is, on information and belief, US Patent Number 9,229,014 does not cover the purported Oxidative Stress Kit, and neither Dr. Crum nor ProImmune owned or controlled any purported know-how related to the Stress Kit. As described above, Dr. Crum is freely sharing of his scientific findings.

176. Counterclaim-Defendants breached the warranties of Section 7.1.3 because, on information and belief, Counterclaim-Defendants have granted, or are under obligations to grant, to third parties licenses, liens, options, encumbrances, or other contingent or non-contingent

rights, titles, or interests in or to the Intellectual Property Rights that conflicts with the rights, if any, granted to the Company,

177. Counterclaim-Defendants breached the Pharmaceutical Commercialization Agreement (“PCA”).

178. Section 9.1 of the PCA states that all parties agree to deal with each other honestly and in good faith. Counterclaim-Defendants failed to meet this obligation including through the numerous misrepresentations discussed above, and specifically through his misrepresentations that Immune Formulation 200 is covered by a patent.

179. Counterclaim-Defendants breached the Innate Operating Agreement. That Agreement provides that ProImmune shall license to the Company pursuant to the COVID-19 Pharmaceutical License Agreement and the Dyslipidemia Pharmaceutical Agreement. Sections 3.1 of each of those Agreements provides for an Exclusive License under the Licensed Patents to make use and sell the Licensed Products. Licensed Products is defined as including Immune Formulation. Counterclaim-Defendants are therefore misrepresenting that Immune Formulation 200 as a Licensed Product, requires a license to the Licensed Patents, when Immune Formulation 200 is not protected by a patent or trade secret.

180. Counterclaim-Defendants breached the COVID-19 and Dyslipidemia Pharmaceutical License Agreements. For example, assuming Immune Formulation 200 is covered by some protectable intellectual property interest provided for in the License Agreements (it is not), whether a U.S. patent or trade secret, part of the License Agreements, then Counterclaim-Defendants have breached Section 14.5(a). That Section warrants that ProImmune is not aware of anything that prohibits its ability to license the Licensed Products. ProImmune, however, had actual knowledge that under the Distribution Agreement, Three Aminos was a distributor of Immune Formulation 200 and therefore could not have granted an

exclusive license to the Company to make, use and sell, the Licensed Products under the Licensed Patents, because Three Aminos already possessed that right. Therefore, it is necessary to determine if Immune Formulation 200 is covered by any of the Licensed Patents to determine the breach of this provision.

181. Despite ProImmune agreeing, on November 7, 2020, to assign and transfer the Intellectual Property Rights to the various joint ventures, on information and belief, when the agreements were executed, ProImmune did not have title to assign the patent. According to the USPTO's website, Dr. Crum did not assign the '014 patent to ProImmune until March 2, 2021. Dr. Crum and ProImmune therefore breached the warranties

182. Due to ProImmune's failure to abide by its contractual obligations and failure to provide the assurance warranted, Three Aminos and Dr. Lile have suffered damages, including, but not limited to, the fact that they have invested substantial time and financial resources into complying with each of these agreements, that otherwise would not have been required due to Counter-Defendants' breach.

COUNT SEVEN

Unjust Enrichment

183. Three Aminos and Dr. Lile reallege and incorporate the foregoing Paragraphs of their Counterclaims as fully set forth herein.

184. Counterclaimants have conferred a substantial benefit on Counterclaim-Defendants, including by providing substantial funding, research, and expertise.

185. Counterclaimants have received nothing in return for these substantial contributions and benefits provided to Counterclaim-Defendants.

186. Counterclaim-Defendants have been unjustly enriched to the detriment of Counterclaimants by way of the substantial contributions and benefits provided to Counterclaim-Defendants by Counterclaimants.

187. WHEREFORE, Counterclaimants are entitled to damages in an amount to be proven at trial for Counterclaim-Defendants' unjust enrichment.

PRAYER FOR RELIEF

WHEREFORE, Counterclaimants pray for judgment as follows:

- a. Dismissal of the Complaint with prejudice;
- b. A declaration that U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734 are invalid;
- c. A declaration that the Immune Formulation 200 product is not covered by any valid U.S. Patent, including, but not limited to U.S. Patent Nos. 9,229,014, RE42,645, and RE39,734.
- d. A declaration that the agreements asserted in the Complaint are unenforceable;
- e. A denial of Plaintiff's requests for relief;
- f. A declaration that this is an exceptional case under 35 U.S.C. § 285 and awarding Counterclaimants its costs, expenses, and attorneys' fees in this action;
- g. A finding that ProImmune and Dr. Crum misappropriated Counterclaimant's Trade Secrets;
- h. An award of damages in an amount to be awarded at trial;
- i. Injunctive relief; and
- j. A grant to Counterclaimants of such other and further relief as the Court may deem just and proper.

JURY DEMAND

Three Aminos and Dr. Lile demand a trial by jury on all issues so triable.

Dated: September 26, 2022

POLSINELLI PC

By:

/s/ Frank T. Spano

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Dated: September 26, 2022

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed with the Clerk of the Court on [DATE] using the CM/ECF System, which will send notification of such filing to all registered ECF users, including the attorneys of record, who have consented to accept this notice of service.

By: s/
Frank T. Spano

VERIFICATION

State of New York

ss.

County of New York

LAURA LILE, M.D., being duly sworn, deposes and says:

She is the Managing Member and Chief Executive Officer of THREE AMINOS, LLC, a defendant in the above-entitled action; that she has read the foregoing answer and counterclaims and knows the factual contents thereof; that the same is true to the best of her individual and corporate knowledge, except as to the matters that may require legal conclusions and those matters alleged upon information and belief.

Dated: September 26, 2022

LAURA LILE, M.D.

[NOTARIZATION]